DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	09/09/2024-09/13/2024
	FEI NUMBER 3011543392

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Vanka Rajeswara Rao, Head - Quality Management

FIRM NAME	STREET ADDRESS
MSN Life Sciences Private Limited, Unit II	Unit-II, Sy. No Parts of 454, 455, 457, 458 & 459
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Chandampet, Telangana, India	API Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

Your firm failed to thoroughly investigate critical deviations and/or the failure(s) of a batch to meet specifications.

Specifically,

A1. Out-of-Specification (OOS)-23064 Investigation was inadequately completed to justify the invalidation of the initial OOS result for Assay by HPLC (Preparation-2) for (b) (4) Lot (b) (4) for stability testing (long term 36 months).

A2. During the investigation for OOS-23064, an analyst was identified to conduct a remeasurement of the sample solutions to determine a probable root cause for OOS-23064. However, per the investigation report (07-OOS23064-R-01), the analyst inadvertently utilized a different sample solution to complete the re-vial testing. Even though the investigation acknowledges the human error, the investigation does not appear to include a new re-vial testing conducted for the true sample solution utilized in the original OOS, and the human error for the re-vial test was not identified and investigated as a separate quality-related event such as a Deviation.

B1. OOS-24006 Investigation was inadequately completed to justify the invalidation of the initial OOS result for

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	Steven A. Brettler -S Digitally signed by Steven A. Brettler -S Date: 2024.09.13 07:50:46 -04'00'	Steven A. Brettler, GDUFA - Investigator	09/13/2024

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Assay by HPLC (Preparation-1) for (b) (4) Lot (b) (4) for stability testing (long term 24 month).

B2. During the investigation for OOS-24006, there was a system suitability failure during the remeasurement testing (re-injection; re-vial; and re-dilution) analysis. Even though the system suitability failure was documented in the investigation, the investigation did not conduct a new remeasurement analysis to determine a root cause and support a re-analysis of the stability sample. Additionally, the quality unit failed to separately investigate the system suitability failure under a Laboratory Incident Form per the firm's SOP CQC-0052-000 titled "GOOD LABORATORY PRACTICES" with an effective date of 01/03/2022 (March 1st, 2022).

C. There were a pattern of OOS Investigations where the quality unit failed to initiate and complete a separate investigation (Laboratory Incident Form) for each suitability failure identified during each investigation including the one specified under B2:
-OOS-24032
--Missing at least one (1) laboratory incident form
-OOS-23093
--Missing at least two (2) laboratory incident forms

OBSERVATION 2

Your quality unit failed to review all critical deviations or non-conformances and related investigations for all API products.

Specifically,

There were quality-related events (OOS, deviations, system suitability failures [invalid and incident]) that were not separately identified for the purposes of review and/or trending purposes to identify quality-related deficiencies. Multiple quality-related events were identified within one (1) quality event investigation which can dilute the total number of quality-related events to review within a given time period.

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OBSERVATION 3

Your quality unit failed to perform one of it's core responsibilities to ensure that critical deviations are investigated and resolved.

Specifically,

Out-of-Trend (OOT) ranges were not calculated and evaluated for a number of specification tests for some of your API products that were: 1) manufactured with less than (b) (4) batches and 2) were not updated within the firm's recently implemented LIMS system. According to your firm's SOP CQC-0003-002 titled "HANDLING OUT-OF-TREND RESULTS" with an effective date of 05/06/2023 (June 5th 2023), section (b) (4) describes a way for handling OOT during API release testing for APIs without trend limits calculated from the (b) (4) batches.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 4
Your production areas fail to provide adequate washing facilities for personnel.

Specifically,

The washing area(s) prior to entry into the cleanroom area(s) of production did not have access to hot water for hand washing.

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